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EXAMINER: ULM, J

ART UNIT: 1812 | PAPER NUMBER: 9

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DATE MAILED: 06/10/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☑ Responsive to communication filed on 03/25/96 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 12 to 29 are pending in the application.
   Of the above, claims 12 & 13 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 14 to 29 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

1) Claims 1 to 13 are pending in the instant application.

2) Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1 to 3 and 6 to 9, drawn to a nucleic acid encoding a human PPARτ, classified in Class 435, subclass 320.1.

II. Claims 4 and 5, drawn to a nucleic acid probe, classified in Class 536, subclass 24.3.

III. Claim 10, drawn to an isolated human PPARτ polypeptide, classified in Class 530, subclass 350.

IV. Claims 11 and 12, drawn to an antibody which binds human PPARτ polypeptide and a hybridoma producing that antibody, classified in Class 530, subclass 388.22.

V. Claim 13, drawn to a human PPARτ binding assay, classified in Class 436, subclass 501.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III and IV are four chemically and structurally different products each of which, if found patentable, would support a separate patent. Distinctness is further shown because each of these products can be made and used without any one or more of the other products.

Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product can be used in a materially different process such as in the affinity purification of PPARτ ligand, anti-PPARτ antibodies or nucleic acid containing an PPARτ effector domain, all of which are materially different from the binding assay that is invention V.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Anthony C. Chen on 16 November of 1995 a provisional election was made with traverse to prosecute the invention of group I, claims 1 to 3 and 6 to 9. Affirmation of this election must be made by applicant in responding to this Office action. Claims 4, 5 and 10 to 13 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

3) Claims 1 to 3 and 6 to 9 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to a nucleic acid encoding a human PPARτ having the entire amino acid sequence presented in SEQ ID NO:2 of the instant specification. The text in the first full paragraph on page 7 of the instant specification indicates that the term "hPPARτ" is not limited to the disclosed amino acid sequence and the text in line

8 on page 12 indicates that a protein need not have the disclosed structure to be encompassed by this term. The instant specification, however, does not identify those amino acid residues in SEQ ID NO:2 which are essential for the biological activity and structural integrity of a human PPARτ and those residues which are either expendable or substitutable. In the absence of this information a practitioner would have to resort to a substantial amount of undue experimentation in the form of insertional, deletional and substitutional mutation analysis of over 490 amino acid residues before they could even begin to rationally design a functional human PPARτ having other than a natural amino acid sequence. The disclosure of a single DNA sequence encoding a single human PPARτ with a natural amino acid sequence is clearly insufficient support under the first paragraph of 35 U.S.C. § 112 for claims which encompass any and all human PPARτ, including mutants thereof, which are encoded by a DNA which whose sequence has 60 contiguous bases in common with SEQ ID NO:1 of the instant application.

The current claim limitations are directly analogous to those of claim 7 of U.S. Patent Number 4,703,008 which were held to be invalid under 35 U.S.C. § 112, first paragraph, for want of enablement in Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd., 18 U.S.P.Q. 2d, 1016 (see page 1026, section D). In that instance, a claim to a nucleic acid encoding a polypeptide having an amino acid sequence sufficiently duplicative of the amino acid sequence of

erythropoietin (EPO) so as to have a specified biological activity was held to be invalid under 35 U.S.C. § 112, first paragraph, for want of enablement. This limitation is directly analogous to the hybridization limitation of the instant claims. The disclosure upon which that claim was based described a recombinant DNA encoding EPO and a few analogs thereof. That disclosure differs from the instant specification because, whereas the instant specification describes a DNA encoding a human PPARτ, it does not describe even a single variant thereof. The court held that what is necessary to support claims of this breadth is a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of the claims. For DNA sequences, that means disclosing how to make and use enough sequences to justify the grant of the claims sought. As indicated, the instant specification is even more limited than the '008 patent because it describes only a single protein and no analogs or mutants thereof and, therefore, provides even less support than the '008 specification for claims of comparable scope and which were held to be invalid in that patent.

See M.P.E.P. §§ 706.03(n) and 706.03(z).

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in

the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

4) Claims 1 to 3 and 6 to 9 are rejected under 35 U.S.C. § 103 as being unpatentable over the Chen et al. publication (BIOCHEM. BIOPHYS. RES. COMM. 196(2):671-677, 29 Oct. 1993, Applicant's reference AN) in view of the Sher et al. publication (Biochem. 32:5598-5604, 1993, Applicant's reference CL). Figure 2 on page 675 of the Chen et al. publication described an isolated DNA encoding a PPARτ which is not encompassed by instant claims 1 to 3 only because it is of murine origin whereas the claimed nucleic acid encodes a PPARτ which is of human origin. Claims 6 to 9 are further distinguished from the DNA of Chen et al. because they encompass a nucleic acid encoding a PPARτ and which is contained within an expression vector.

The Sher et al. publication has been relied upon because its abstract shows that the existence and structure of a murine PPAR gene, and the protein encoded thereby, was predictive of the existence of a corresponding human PPAR gene and protein. The text in the third full paragraph on page 5599 of this publication establishes that the isolation of a cDNA encoding a human PPAR be screening a human cDNA library with a DNA encoding a murine PPAR

was fairly taught in the art of molecular biology prior to the making of the instant invention. Because an artisan was well aware that the ultimate utility of a PPARτ like the one that was described by Chen et al. would be found in its applicability to human subjects, they would have found the isolation of a cDNA encoding human PPARτ by screening a human cDNA library with the cDNA encoding the murine PPARτ in a manner directly analogous to that which was employed by Sher et al. to isolate a DNA encoding the human counterpart of the murine PPAR described therein to permit the characterization of that protein at the molecular level to have been prima facie obvious at the time that the instant invention was made. To have subsequently placed that human cDNA into an expression vector to permit it functional characterization as described in the first paragraph on page 5601 of Sher et al. was also fairly taught by this combination of references at that time. Because the abstract of the Sher et al. publication and Figure 1 on page 673 of the Chen et al publication established that the amino acid sequences of homologous PPARs from different vertebrates were known to be highly conserved at that time, an artisan had more than a reasonable expectation of successfully producing a DNA encoding the human homolog of the murine PPARτ of Chen et al. by employing those cDNA isolation techniques of Sher et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm at telephone number (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are

unsuccessful, the examiner's supervisor, G. D. Draper can be reached on (703) 308-4232. The fax phone number for Art Unit 1812 is (708) 308-0294.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PATENT EXAMINER
GROUP 1800